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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re the Application of: **Nobushige DOISAKI et al.**

Art Unit: **1655**

Application Number: **10/535,413**

Examiner: **Randall O. Winston**

Filed: **November 17, 2005**

Confirmation Number: **5903**

For: **COMPOSITION CONTAINING ORGANIC SUBSTANCE HAVING DOUBLE
BOND WITH IMPROVED OXIDATIVE STABILITY**

Attorney Docket Number: **052572**
Customer Number: **38834**

SUBMISSION OF APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

July 8, 2008

Sir:

Appellant submit herewith an Appeal Brief in the above-identified U.S. patent application.

Attached please find a check in the amount of \$510.00 to cover the cost for the Appeal Brief.

If any additional fees are due in connection with this submission, please charge our Deposit Account No. 50-2866.

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
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APPEAL BRIEF FOR THE APPELLANT

Ex parte Nobushige DOISAKI et al. (Appellant)

**COMPOSITION CONTAINING ORGANIC SUBSTANCE HAVING
DOUBLE BOND WITH IMPROVED OXIDATIVE STABILITY**

Serial Number: **10/535,413**

Filed: **November 17, 2005**

Appeal No.:

Group Art Unit: **1655**

Examiner: **Randall O. Winston**

Submitted by:

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BRIEF ON APPEAL

(I) REAL PARTY IN INTEREST

The real party in interest is **NIPPON SUISAN KAISHA, LTD.**, by an assignment recorded in the U. S. Patent and Trademark Office on **November 17, 2005** at Reel **017237**, Frame **0254**.

(II) RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to appellant, appellant's legal representative, or assignee that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(III) STATUS OF CLAIMS

The final action indicates that claims 1-3 and 5-20 are rejected. However, claims 2 and 3 have been cancelled before the final action was issued.

Therefore, claims 1 and 5-20 are rejected and appealed.

(IV) STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final rejection.

(V) SUMMARY OF CLAIMED SUBJECT MATTER

The object of the present invention is to provide a composition of organic substance, particularly a polyunsaturated fatty acid or its ester having a double bond which has highly improved oxidative stability (page 6, line 25 to page 7, line 3).

The inventors of the present invention have conducted intensive research in order to enhance the oxidative stability of oils and fats (oils and fats containing a high proportion of polyunsaturated fatty acid, such as oils of fish and aquatic animals). As a result, the inventors found that the oxidative stability of oils and fats is greatly enhanced by adding an antioxidative component of sesame, such as sesamol, and an ascorbic acid or ascorbyl fatty acid ester in combination. In addition, the present inventors found that the antioxidant properties of antioxidative sesame component other than sesamol are also extremely enhanced by combination with ascorbic acid or ascorbyl fatty acid ester, and thus accomplished the present invention (page 7, lines 4-17).

The composition having oxidative stability contains (1) polyunsaturated fatty acid or its salt or ester having a double bond, an antioxidative sesame component, and ascorbic acid or an ascorbyl fatty acid ester (page 7, lines 18-23) as set forth in independent claim 1.

The present invention can make it easy to add a polyunsaturated fatty acid or its salt or ester to various compositions such as medical drugs, cosmetic preparations, food, which conventionally has been limited. Since the antioxidative sesame component and ascorbic acid or an ascorbyl fatty acid ester used in the present invention is ingested as food, a safe antioxidant can be provided for food as well (page 10, lines 5-18).

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(VI) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-3 and 5-20 are obvious under 35 USC 103(a) over Kataoka et al. (US 6235331) and/or Granata (WO02/058793) in view of Chavali et al. (US 20010031275, DWPI Abstract), Maguire et al. (DWPI Abstract, 1995-054394), Chen et al. (US 20020156051, DWPI Abstract) and Wechter (US 6242479).

(VII) ARGUMENT

1. Cited References Do Not Teach Or Suggest The Combination Of Ingredients.

Claim 1 recites as follows:

A composition having oxidative stability comprising:
polyunsaturated fatty acid or its salt or ester,
an antioxidative sesame component which is purified from sesame or
synthesized, and
ascorbic acid or an ascorbyl fatty acid ester.

None of Kataoka et al, Granata, Chavali et al, Maguire et al, Chen et al and Wechter teach or suggest the particular combination of ingredients of the present invention. The Examiner alleged in the previous Office Action as follows:

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify either Kataoka or Granata composition's teachings to include the active ingredients of sesamol, ascorbic acid or ascorbyl fatty acid ester and tocopherol as taught by Chavali, Maguire, Chen and Wechter within Kataoka or Granata composition's teachings because the above combined teachings would create the claimed composition to treat cardiovascular disorders. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, **in order to**

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form a third composition to used for the same purpose..." The adjustments of other conventional working conditions (i.e. the claimed active ingredient's amounts within its composition, the substitution of one form of the composition for the another and fish oil form), is deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Please note that the patentability of a product does not depend upon the method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made by a different process" (see, e.g. MPEP 2113).

However, in the present invention, the antioxidative sesame component and ascorbic acid or an ascorbyl fatty acid ester are not added to modify the composition of Kataoka or Granata, or to form a third composition to be used for the same purpose, or to adjust other conventional working conditions. Instead, these are added to form a third composition which has dramatically improved oxidative stability. The MPEP also explains as follows:

"A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness ... of the claims at issue." *In re Corkill*, 711 F.2d 1496, 226 USPQ 1005 (Fed. Cir. 1985). In *Corkhill*, the claimed combination showed an additive result when a diminished result would have been expected. This result was persuasive of nonobviousness even though the result was equal to that of one component alone. **Evidence of a greater than expected result may also be shown by demonstrating an effect which is greater than the sum of each of the effects taken separately** (i.e., demonstrating "synergism"). *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). However, a greater than additive effect is not necessarily sufficient to overcome a *prima facie* case of obviousness because such an effect can either be expected or unexpected. Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. *Ex parte The NutraSweet Co.*, 19 USPQ2d 1586 (Bd. Pat. App. &

Inter. 1991) (Evidence showing greater than additive sweetness resulting from the claimed mixture of saccharin and L-aspartyl-L-phenylalanine was not sufficient to outweigh the evidence of obviousness because the teachings of the prior art lead to a general expectation of greater than additive sweetening effects when using mixtures of synthetic sweeteners.).

(MPEP 716.02(a)I, emphasis added). Thus, an effect which is greater than the sum of each of the effects taken separately can be evidence of a greater than expected result. The disclosure of the present application sufficiently shows not just greater-than-expected results but dramatically improved results which were not expected before the present invention.

2. *Prima Facie* Case Of Obviousness Has Been Effectively Rebutted By Factual Evidence.

The significance of the synergistic effect is shown by the examples in the present disclosure. For example, Fig. 1 shows the absorbed oxygen in two days after storage at 60°C for fish oil containing 0.5 wt% δ-tocopherol. The addition of sesamol alone or ascorbyl palmitate alone does not significantly prevent the absorption of oxygen. However, the addition of the combination of sesamol and ascorbyl palmitate dramatically decreases the absorption of oxygen.

Similarly, Fig. 5 shows the absorbed oxygen in four days after storage at 60°C for fish oil containing 0.5 wt% δ-tocopherol. The addition of sesame extract alone or ascorbyl palmitate alone does not significantly prevent the absorption of oxygen. However, the addition of the combination of sesame extract and ascorbyl palmitate dramatically decreases the absorption of oxygen.

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Also, Fig. 14 shows a comparison of the combination of sesamol and ascorbyl palmitate with BHT, which is a commonly used antioxidant. The combination of 1.0% sesamol and 0.5% ascorbyl palmitate yields much better results than 10% of BHT.

Thus, significant synergistic effect of the present invention is shown by the examples in the present disclosure.

The present inventors have been studying over the years fish oil containing polyunsaturated fatty acids. The most crucial issue in handling fish oil has always been antioxidation of fish oil which has many double bonds and is highly oxidizable. There was no effective antioxidation for those oxidizable substances for a long time. Also, for the sake of safety, there is a limitation for the type of antioxidants to be used especially in foods. Also, there is a trend of preference of naturally-occurring food-derived antioxidants rather than synthetic ones.

Also, there is no established method of predicting synergistic effects of antioxidants. Thus, trial and error is a common practice of developing a suitable combination of antioxidants. From extensive study of various combinations of antioxidants, the present inventors have found that the combined use of sesamol, which is known as an antioxidative sesame component, and ascorbyl palmitate produce an unexpectedly highly synergistic effect. Such highly synergistic effect was not expected before the invention.

It is not practically possible to test every combination because there are enormous numbers of antioxidant combinations. Therefore, it is not easy for a skilled person to discover an

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effective combination. The present invention is a remarkable achievement for the manufacture of a composition having oxidative stability.

3. Unexpected Results Not Limited To Specific Amounts Of Active Ingredients.

In the Final Office Action, the Examiner alleged as follows:

Applicant argues Kataoka et al, Granata, Chavali, Maguire, Chen and Wechter do not teach or suggest the particular combination of ingredients because the combination of references suggest the particular combination of ingredients have greater than expected results as shown in Figure 1. Thus, an effect which is greater than the sum of each of the effects taken separately can be evidence of a greater than expected result. The disclosure of the present application sufficiently shows such unexpected results.

Although Applicant argues that the disclosure of the present application sufficiently shows such unexpected results, it appears to examiner that **applicant has not claimed any specific effective amounts and/or ranges of active ingredients within its claimed composition to determine whether applicants' claimed composition invention demonstrates unexpected results and synergism.** What specific effective amounts and/or ranges of active ingredients within applicants' claimed composition of claims 1-3 and 5-20 produce unexpected results and synergism?

As discussed above, Kataoka et al, Granata, Chavali et al, Maguire et al, Chen et al and Wechter do not teach or suggest the particular combination of ingredients. Also, as already discussed, the embodiments show effects which are dramatically greater than the sum of each of the effects taken separately, which MPEP 716.02(a) explains as a possible persuasive result. The disclosure of the present application sufficiently shows such unexpected results. Thus, the *prima facie* case of obviousness has been effectively rebutted by factual evidence by the explanation of

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the embodiments. The Examiner does not deny the unexpectedness of the results shown in the present embodiments.

Nevertheless the Examiner alleges that applicant has not claimed any specific effective amounts and/or ranges of active ingredients. It appears that the Examiner assumes that the unexpected results are limited to specific amounts or ranges of active ingredients. However, it would be rather unusual for a person of ordinary skill in the art to assume that the synergistic antioxidantizing effects will disappear in the amounts or ranges other than those shown in the embodiments. A person of ordinary skill in the art would assume that if the amount becomes less, **the synergistic antioxidantizing effects will still remain comparing with adding antioxidative sesame component alone or ascorbic acid or an ascorbyl fatty acid ester alone.** Thus, it is natural for a person of ordinary skill in the art to conclude similar results will be obtained for the amounts or ranges other than those shown in the embodiments. The Examiner has not shown any reasonable basis for the assumption.

The present invention is based on the present inventors' discovery that the combination of an antioxidative sesame component and ascorbic acid or an ascorbyl fatty acid ester shows remarkable synergistic antioxidantizing effects.

For at least these reasons, claim 1 patentably distinguishes over Kataoka et al, Granata Chavali et al, Maguire et al, Chen et al and Wechter. Claims 5-20, all depending from claim 1, also patentably distinguish over Kataoka et al, Granata, Chavali et al, Maguire et al, Chen et al and Wechter for at least the same reasons.

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CONCLUSION

For at least the foregoing reasons, the Examiner erred in finding that Claims 1-3 and 5-20 are obvious under 35 USC 103(a) over Kataoka et al. and/or Granata in view of Chavali et al., Maguire et al., Chen et al. and Wechter. The Honorable Board is respectfully requested to reverse the rejection of the Examiner.

If this paper is not timely filed, Appellant hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 50-2866, along with any other additional fees that may be required with respect to this paper.

Respectfully submitted,

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(VIII) CLAIMS APPENDIX

1. A composition having oxidative stability comprising:
polyunsaturated fatty acid or its salt or ester,
an antioxidative sesame component which is purified from sesame or synthesized, and
ascorbic acid or an ascorbyl fatty acid ester.
- 2-3. (Cancelled).
4. A composition according to claim 1, wherein the poly unsaturated fatty acid contains at least one of eicosapentaenoic acid and docosahexaenoic acid.
5. A composition according to claim 1, wherein the ester of the poly unsaturated fatty acid is a triglyceride containing the poly unsaturated fatty acid as a constituent, or a lower alcohol ester of the poly unsaturated fatty acid.
6. A composition according to claim 1, wherein the ester of the poly unsaturated fatty acid is added in a form of refined fish oil.
7. A composition according to claim 1, wherein the antioxidative sesame component is at least one of the substances represented by peaks detected by high-performance liquid chromatography using an electrochemical detector at elution times of about 2.66, 3.40, 3.84, 4.57, 4.98, 5.82, 7.00, 8.67, 9.84, 11.24, 12.29, 12.49, 13.36, 14.04, 14.32, 14.74, 15.22, 15.60, 15.82,

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16.34, 16.98, 18.10, 18.43, and 34.91 minutes.

8. A composition according to claim 1, wherein the antioxidative sesame component is extracted from sesame, sesame oil, or sesame residue, using a solvent, a lipid, or an emulsifier singly or in combination.

9. A composition according to claim 1, wherein the antioxidative sesame component is at least one selected from the group consisting of sesamol, sesaminol, episesaminol, pinoresinol, epipinoresinol, syringaresinol, samine, sesamolinol, and 2,3-di(4'-hydroxy-3'-methoxybenzyl)-2-buten-4-oxide.

10. A composition according to Claim 1, wherein the antioxidative sesame component is sesamol.

11. A composition according to Claim 1, wherein the antioxidative sesame component is extracted from sesame residue.

12. A composition according to Claim 11, wherein the antioxidative sesame component extracted from sesame residue is extraction using a solvent, a lipid, or an emulsifier singly or in combination.

13. A composition according to claim 1, wherein the ascorbyl fatty acid ester contains ascorbyl palmitate or ascorbyl stearate.

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14. A composition according to claim 1, wherein the ascorbic acid or the ascorbyl fatty acid ester is contained in an excessive amount more than the amount soluble in the poly unsaturated fatty acid or its salt or ester.
15. A composition according to claim 14, wherein the excessive amount of the ascorbic acid is in a powder or solid form.
16. A composition according to claim 1, further comprising tocopherol.
17. A composition as set forth in claim 1, wherein the composition is contained in a food.
18. A composition as set forth in claim 1, wherein the composition is contained in a powdered oil or fat.
19. A composition as set forth in claim 1, wherein the composition is contained in a powdered baby milk.
20. A composition as set forth in claim 1, wherein the composition is contained in a health food.

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(IX) EVIDENCE APPENDIX

None Presented.

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(X) RELATED PROCEEDINGS APPENDIX

No Related Proceedings.